REMARKS

Allowable Subject Matter

In the Office Action, the Examiner withdraws the previous indicated allowability of claims 2, 3, 5 and 6. As explained below, these claims are still allowable over the newly discovered reference(s) to Sahota and Haverkost et al., and it is respectfully requested that these claims again be allowed.

Claim Rejections - 35 USC §102

In the Office Action, the Examiner rejects Claims 2 and 4-12 under 35 USC §102(b) as being anticipated by Sahota (US 2003/0181973 A1). This rejection is respectfully traversed.

Independent Claim 2 of the present application is directed to a balloon catheter having an expandable balloon located at the distal end portion of the catheter, with a pouch disposed on at least a portion of the balloon, wherein the pouch expands and contracts with the inflation and deflation of the balloon, and wherein an area between the pouch and the portion of the expandable balloon is adaptive to receiving an agent when the balloon is not expanded. The expandable balloon has an annular ridge at both the distal and proximal end of the balloon with the pouch located between the annular ridges. The claimed balloon catheter is for inserting into the vascular system of a human wherein there is blockage (usually from plaque) within a vessel. The uninflated balloon on the distal end of the catheter is positioned at the spot of the blockage. The balloon is then inflated which disrupts and flattens the plaque against the arterial wall, and stretches the arterial wall, resulting in enlargement of the intraluminal passageway and increased blood flow. This breaks-up the plaque and clears the blockage in the vessel. At the same time as the balloon is inflating, the pouch on the balloon is stretching and expanding. The expansion of the balloon then forces the drug through the

pouch and into the vessel at the point of the balloon expansion (i.e. the blockage in the vessel). Thereafter, the balloon with pouch is deflated and removed from the body. This is reflected in Claim 10 which is directed to a method of delivery of a drug to a selected site within a vascular system of a patient using the claimed catheter of Claim 2. One purpose of the claimed catheter and method is to break-up the blockage without having to permanently leave a structure without the vessel.

In contrast, Sahota is directed to a stent. A stent is intended to be permanently left within the vessel, which is very different than the balloon catheter device of the claimed invention. In the Office Action, the Examiner contends that Sahota discloses a pouch 700 (fig. 7J) disposed between the annular ridges on the balloon. However, in contrast to the balloon catheter of independent Claim 2 and Claim 10 of the present application, the film in Sahota is either attached to the stent or formed on the stent (see e.g. [0080] in Sahota). With the device of Sahota, the stent is permanently placed in the vessel with the attached film. The film then dissolves and is absorbed by the body, releasing the drug at the treatment site (see e.g. [0081]). Hence, the film (i.e. the alleged pouch) is left in the body with the stent, unlike the pouch of the balloon catheter of Claims 2 and 10 of the present application wherein the balloon and pouch are removable or removed from the body.

Therefore, Sahota does not disclose or suggest the balloon catheter of independent Claim 2 or Claim 10 and those claims dependent thereon. Accordingly, these claims are patentable thereover, and it is respectfully requested that this rejection be withdrawn.

Claim Rejections - 35 USC §103

The Examiner also rejects Claims 3 and 13-15 under 35 USC §103(a) as being unpatentable over Sahota in view of Haverkost et al. (US 2003/0139806 A1). This rejection is also respectfully traversed.

For at least the reasons explained above, independent Claim 3 is also not disclosed or suggested by Sahota and is patentable thereover.

Additionally, the Examiner admits that Sahota does not disclose a pouch made of ePTFE. The Examiner, however, cites Haverkost as teaching "that it is known to make pouches(stents) of ePTFE" and that "it would have been obvious to modify Sahota's pouch(stent) by making its pouch(stent) of ePTFE, since Haverkost teaches that it is all well know in the art its use to facilitate ingrowth, and its minimal impact on the body." Applicant respectfully disagrees.

As explained above, the alleged "pouch" in Sahota is a film which is attached to the stent and left in the body to dissolve, be absorbed by the body and release the drug while dissolving. Haverkost, however, is directed to a composite intraluminal prosthesis which includes a layer of ePTFE. Unlike Sahota, Haverkost states that the polymers which are particularly useful in the invention of Haverkost are polymers which "are particularly resistant to degradation in the body over time and exhibit exceptional resistance to cracking in vivo." (see [0039] in Haverkost).

Hence, one skilled in the art would not combine Sahota with Haverkost as they teach away from one another (i.e. one teaching (Sahota) that the film is to dissolve in the body to release the drug and the other teaching (Haverkost) that the material is particularly resistant to degrading and the body - and therefore would provide no mechanism for release of the drug). Therefore, one skilled in the art would not combine these two teachings. Accordingly, the combination of these references to arrive at the claimed invention is not proper, and the rejection based thereon should be withdrawn.

CONCLUSION

Therefore, for at least the above-stated reasons, the present application is in an allowable condition and should be allowed.

Please charge our deposit account 50/1039 for any further fee for this amendment or new claims.

Favorable reconsideration is earnestly solicited.

Respectfully submitted,

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